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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

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EPA

Pesticide Fact Sheet

Name of Chemical: PHOSALONE
Reason for Issuance: REGISTRATION STANDARD
Date Issued: NOVEMBER 30, 1987
Fact Sheet Number: 148

1. DESCRIPTION OF CHEMICAL

Generic Name (Chemical): S-6-chloro-2,3-dihydro-2-oxobenzoxazol-3-yl methyl 0,0-diethyl phosphorodithioate

Common Name: Phosalone (ANSI)

Other Chemical Nomenclature:
- °S-[(6-chloro-2-oxo-3(2H)benzoxazolyl)methyl] 0,0-diethylphosphorodithioate;
- °0,0-diethyl phosphorodithioate S-ester with 6-chloro-3-(mercaptomethyl)2-benzoxazolinone;
- °0,0-diethyl-S-[(6-chloro-2-oxobenzoxazolin-3-yl) methyl]phosphorodithioate;
- °S-[6-chloro-3-(mercaptomethyl)-2-benzoxazolinone] 0,0-diethylphosphorodithioate;
- °0,0-diethyl-S-[6-chloro-3-(mercaptomethyl)-2-benzoxazolinone] phosphorodithioate.

Trade Names: Azonfene, Benzofos, RP11974, Rubitox, and Zolone.

EPA Shaughnessy Code: 097701

Chemical Abstracts Service (CAS) Number: 2310-17-0

Year of Initial Registration: 1974

Pesticide Type: Insecticide/Acaricide

Chemical Family: Organophosphate

U.S. and Foreign Producers: Rhone-Poulenc, Inc.

2. USE PATTERNS AND FORMULATIONS

Application Sites: Nut crops, citrus crops, pome fruits, stone fruits, grapes, potatoes, artichokes, roses, and arborvitae.
Formulation Types: Technical, Emulsifiable Concentrate and Wettable Powder.
Application Methods: Foliar: ground and aerial application.

3. SCIENCE FINDINGS

Summary Science Statement

Phosalone may have an adverse impact on birds and aquatic organisms resulting from all use patterns, excluding ornamentals. Aquatic and terrestrial field studies are required to determine the potential risks to these organisms. Laboratory data show that technical phosalone is highly toxic to fish and aquatic invertebrates.

The toxicological profile of the end-use products places them in Toxicity Category II for primary eye irritation, acute oral and dermal exposures. The end-use products were only mildly irritating to the skin when tested for dermal irritation. The products were characterized as weak dermal sensitizers. Phosalone can cause adverse effects to persons entering treated fields and to persons involved in the preparation and application of this pesticide. Preliminary data show that groundwater contamination is unlikely, but the Agency is unable to conduct a full assessment due to data gaps.

Chemical/Physical Characteristics of the Technical Material

Physical State: Crystalline solid

Color: White

Molecular weight and formula: 367.8 gms-$C_{12}H_{15}ClNO_4PS_2$

Melting Point: 45-47°C

Density: 1.391 g/ml at 20°C

Vapor Pressure: $\leq$ 0.5 x 10^{-6} mm Hg at 24°C and 16.4 x 10^{-6} at 60°C

Solubility: At 20°C: 1.7ppm in water; 20 g/100 ml in methanol and ethanol; and 10g/100ml in acetone, benzene, cyclohexanone, acetonitrile, xylene, toluene, dioxane, chloroform, and methyl chloride.

Stability: Very stable under normal laboratory conditions for a period of 2 years.

Toxicology Characteristics (Technical Material)

Acute Oral: Toxicity Category II (90 and 125 mg/kg in female and male rats respectively).

Acute Dermal: Toxicity Category II (LD50 > 350 mg/kg for both males and females).

Acute Inhalation: Waived for technical, particles analyzed were determined not to be within the respirable range ($\leq$ 15 microns).

Primary Dermal Irritation: Toxicity Category IV (PDIS-0.77, mildly irritating to intact and abraded skin).

Primary Eye Irritation: Data gap.

Skin Sensitization: Data gap.

Delayed neurotoxicity: Negative in hens.

Subchronic Oral (non-rodent): Data gap.

Oncogenicity: Data gap.

Chronic Feeding: NOEL for RBC inhibition in the rat is 25 ppm.

Metabolism: Data gap

Teratogenicity: Data gap

Reproduction: Data gap

Mutagenicity: Data gap for point mutation assay in mammalian cells, structural chromosomal aberration, and other genotoxic effects.

Major routes of exposure: Dermal and respiratory exposure to mixers, loaders, applicators, and fieldworkers.

Environmental Characteristics

Phosalone is stable at pH 5 and 7, but is hydrolyzed at a pH of 9 with a half-life of 9 days. Artificial light accelerated degradation in buffered solution at a pH of 5 and in soil. Aerobic soil metabolism studies demonstrate half-life values of 1-7 days. Field dissipation studies showed half-life values of 1-9 weeks. Phosalone was essentially immobile in a soil column test. Based upon this preliminary data phosalone appears unlikely to contaminate ground water. It exhibited moderate accumulation in the bluegill sunfish, with rapid dissipation in untreated waters.

Ecological Characteristics (Technical grade)

Avian Oral Toxicity:	Slightly toxic to waterfowl (acute oral toxicity value: mallards > 2150 mg/kg).
Avian Dietary Toxicity: (8-Days)	Slightly toxic to waterfowl and upland-game birds (subacute toxicity values: mallards 1659 ppm and bobwhite quail 2033 ppm).
Freshwater Fish Acute: Toxicity (96-Hours)	Very highly toxic to warmwater fish and and highly toxic to coldwater fish (acute LC values: 0.05 ppm bluegill and 0.63 ppm rainbow trout).
Freshwater Invertebrate: Toxicity (48-Hours)	Very highly toxic to aquatic invertebrate (acute EC value: 0.0012 ppm Daphnia magna)

4. Tolerance Reassessment

Tolerances have been established for phosalone on a variety of raw agricultural commodities, in meat, fat and meat byproducts (40 CFR 180.263) and in processed food (21 CFR 193.340) and feed (21 CFR 561.300).

Tolerances for the following commodities are adequately supported: potatoes, citrus, apples, pears, apricots, cherries, nectarines, peaches, plums (fresh prunes), dried prunes, tree nuts, almond hulls, grapes, raisins, artichokes, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses and sheep.

Additional data are required to assess the need for food/feed additive tolerances for the following products processed from raw agricultural commodities bearing measurable, weathered residues: potato granules or flakes, chips, and wet and dry peels, raisin waste and grape juice.

The nature of the residues in both plants and animals are not adequately understood. If, on receipt of the required metabolism data, the Agency determines that residues in addition to the parent require regulation, additional methods for data collection and enforcement may be required.

Crop group tolerances may be proposed for the Pome Fruit Group at 10 ppm and for the Stone Fruit Group at 15 ppm.

The Agency has established a Provisional Acceptable Daily Intake (PADI) at 0.0025 mg/kg/day based on a 6-month dog feeding study in which plasma cholinesterase activity was depressed. Because a NOEL was not established in this study a 100 fold uncertainty factor has been used rather than the 10 fold factor normally applied for cholinesterase inhibition.

5. Summary of Regulatory Positions and Rationales

°Phosalone is not being placed into Special Review at this time. Although the Agency is concerned about the potential adverse impact of phosalone on birds and aquatic organisms resulting from the agricultural use patterns, aquatic and terrestial field studies are needed in order to evaluate the potential risks to these species.

°The Agency has sufficient data (analysis of pesticides with similar uses were found to be in jeopardy) to indicate that the current use patterns of phosalone may affect endangered species. Endangered species labeling is reserved pending concurrence from the Fish and Wildlife Service.

°The Agency is classifying all Phosalone end use products as Restricted Use Pesticides; except for products packaged and labeled solely for use around the home. Products containing phosalone for use on cherries and citrus are restricted due to avian hazards. All use patterns are restricted due to aquatic toxicity. The estimated environmental concentrations exceed the LC50 value for fish and the EC50 value for aquatic invertebrates, and the NOEL values for avian species.

°The Agency is imposing a 6-month rotational crop restriction for small grains and a 12-month rotational crop restriction for leafy vegetables and root crops.

•No significant new tolerances or new food uses will be granted until the Agency has received sufficient data to evaluate the dietary exposure of phosalone.

•The Agency will retain the 24-hour reentry interval imposed in the 1981 Registration Standard. This reentry interval will be retained until the required reeentry data are received and evaluated. Data will be reviewed on a priority basis because of reported poisoning incidents in California.

•The Agency will require that end use products bear label statements to protect mixers, loaders, applicators, flaggers, and fieldworkers.

•Preliminary data indicate that groundwater contamination is unlikely. The Agency is requiring environmental fate studies to fully characterize phosalone's fate in the environment.

6. SUMMARY OF OUTSTANDING DATA REQUIREMENTS

	Time Frame
Toxicology	
Primary Eye Irritation	9 Months
Dermal Sensitization	9 "
Acute Inhalation	9 "
Subchronic oral toxicity--Dog (for cholinesterase effects)	12 "
Oncogenicity--rat	50 "
Teratogenicity--(rat and rabbit)	15 "
Reproduction--(rat)	39 "
Mutagenicity	12 "
Metabolism study	12 "
Dermal Absorption (rat)	9 "
Environmental Fate/Exposure	
Aged leaching study	12 "
Rotational Crop (Confined)	12 "
Foliar dissipation study	15 "
Spray Drift	12 "
Soil Dissipation	27 "

Fish and Wildlife

Avian reproduction	24 Months
Actual field testing- birds and mammals (citrus)	30 "
Simulated or Actual field testing-aquatic organisms	48 "
Acute toxicity to Estuarine and Marine organisms	12 "
Fish early life stage and aquatic invertebrate life cycle	15 "
Acute toxicity to Freshwater Invertebrate	9 "

Residue Chemistry

Animal and Plant metabolism	18 Months
Storage stability	15 "
Processing studies for potatoes and grapes	24 "
Residue data (tea)	18 "

Product Chemistry 6-15 Months

7. CONTACT PERSON AT EPA

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DISCLAIMER: The information presented in this Chemical Information Fact Sheet is for informational purposes only and may not be used to fulfill data requirements for pesticide registration and reregistration.

COMMUNICATIONS STRATEGY FOR PHOSALONE

ACTION: Registration Standard, issued under the provisions of Section 3(g) of FIFRA

PROPOSED ISSUANCE DATE: October, 1987

AGENCY REVIEW:

This document has been reviewed by OPPE, OGC, OCM, AA/OPTS, and OPP offices (RD, HED, PMSD, BUD).

GROUPS AFFECTED BY THE STANDARD:

This document requires registrants of all products containing phosalone to generate data to replace missing or inadequate studies, and to revise labels to reflect the additional precautions required in the standard. There are 4 FIFRA section 3 end-use products, one technical product, and 1 FIFRA section 24(c) special local need registrations. The basic producer of phosalone is Rhone-Poulenc, Inc.

OTHER GROUPS TO RECEIVE COPIES OF THE STANDARD:

Copies of the Standard will be sent by the Registration Support and Emergency Response Branch (RSERB), RD to EPA regional offices, Agriculture Canada, and Health Canada. Copies of the standard will be sent by OPP's state coordinator to each state. Additional copies are available to the public

through NTIS. The public is notified of the availability of the Registration Standard through periodic announcement in the Federal Register.

BACKGROUND INFORMATION:

The fact sheet, attached, summarizes the Registration Standard. RSERB maintains a mailing list for the fact sheet. An announcement will be placed in the Federal Register shortly which will provide people the opportunity to put their name on the fact sheet mailing list.

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